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Attorney's Docket No. 033432-01500/290

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Pat	ent Application of)						
Annapurna JETTY et al.			Group Art Unit: 1614					
Application No.: 10/098,505)			Examiner: Lilling J. Herbert					
Filed: N	March 18, 2002	,	Confirmation No.: 4407					
(PROCESS FOR THE PREPARATION () OF BETA-KETO ALIPHATIC ACID () ESTER ()							
	AMENDMENT/REPLY TRANSMITTAL LETTER							
P.O. Box	sioner for Patents x 1450 ria, VA 22313-1450							
Encl	Enclosed is a reply for the above-identified patent application.							
. []] A Petition for Extension of Time is also enclosed.							
[]	A Terminal Disclaimer and the [] \$55.00 (2814) [] \$110.00 (1814) fee due under 37 C.F.R. § 1.20(d) are also enclosed.							
[]	Also enclosed is/are							
[]	Small entity status is hereby claimed.							
[]	Applicant(s) request continued examination under 37 C.F.R. § 1.114 and enclose the [] \$375.00 (2801) [] \$750.00 (1801) fee due under 37 C.F.R. § 1.17(e).							
	[] Applicant(s) previously submitted, on, for which continued examination is requested.							
[]	Applicant(s) request suspension of action by the Office until at least, which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.							
[]	A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also enclosed.							
[X]	No additional claim fee is required.							

Amendment/Reply Transmittal Letter
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[] An additional claim fee is required, and is calculated as shown below:

	No. OF CLAIMS	A M E N D E D HIGHEST NO. OF CLAIMS PREVIOUSLY PAID FOR	EXTRA CLAIMS	RATE	ADDT'L FEE
Total Claims		MINUS =		× \$18.00 (1202) =	
Independent Claims		MINUS =		× \$84.00 (1201) =	
If Amendment adds mu	ltiple depend	lent claims, add \$28	0.00 (1203)		
Total Amendment Fee					
If small entity status is	claimed, sub	tract 50% of Total A	Amendment F	ee	
TOTAL ADDITIONA	L FEE DUE	FOR THIS AMEN	NDMENT		

[]	A claim f	fee in the	amount of \$	is enclosed.
[]	Charge \$		to Deposit Account N	lo. 02-4800.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: May 29, 2003

Martin A. Bruehs

By: \subseteq

Registration No. 45,635

P.O. Box 1404 Alexandria, Virginia 22313-1404 (703) 836-6620



Patent Attorney's Docket No. <u>033432-015</u>

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Pa	tent Application of)		
Annapu	rna JETTY et al.)	Group Art Unit: 1614	
Applica	tion No.: 10/098,505)	Examiner: Lilling J. Herbert	77
Filed: 1	March 18, 2002)	Confirmation No.: 4407	
(PROCESS FOR THE PREPARATION OF BETA-KETO ALIPHATIC ACID ESTER)))	TER 1600/2900	

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the Requirement for Restriction issued on April 29, 2003, Applicants hereby elect, with traverse, the invention of Group II, claims 9-10, drawn to an antibiotic compound β -keto aliphatic acid ester isolated from *Bacillus sp.* IICT 001 and a pharmaceutical composition comprising an effective amount of a β -keto aliphatic acid ester isolated from *Bacillus sp.* IICT 001, respectively.

Reconsideration of the Requirement for Restriction is respectfully requested in light of the following remarks.

For proper restriction between patentably distinct inventions:

(1) The inventions must be independent or distinct as claimed; and

(2) There <u>must</u> be a <u>serious</u> burden on the Examiner if restriction is not required. See M.P.E.P. §803.

The Examiner takes the position that:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. §806.05(f)). In the instant case, the product as claimed can be made by another and materially different process, e.g., by synthetic methods or by employing a different microorganism *Bacillus sp substrate*.

See Official Action at page 2.

Applicants submit that the Requirement for Restriction should be withdrawn because the search and examination of the inventions of Group I and II would be substantially coextensive.

In particular, in the present application, Group I is directed to a process for preparation of a β -keto aliphatic acid ester, which comprises growing a *Bacillus sp.* IICT 001 in growth medium for a period of at least three to four days to obtain broth, extracting said broth with organic solvent, removing the solvent and purifying the β -keto aliphatic acid ester. Group II is directed to an antibiotic compound β -keto aliphatic acid ester isolated from *Bacillus sp.* IICT 001 and a pharmaceutical composition comprising an effective amount of a β -keto aliphatic acid ester isolated from *Bacillus sp.* IICT 001. Because it is likely that the results of the search of the claims of Group II would produce references that disclose both antibiotic compounds of β -keto aliphatic acid esters and

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pharmaceutical compositions comprising such alphatic acid esters and processes for the preparation of such alphatic acid esters, Applicants believe that the search and examination of the subject matter of Group II would likely encompass a search for the subject matter of Group I and any additional search would not impose a serious burden on the Examiner.

Thus, Applicants submit that an undue burden would not be placed on the Examiner by including each of the inventions within a single application.

Accordingly, for at least these reasons, and in order to avoid unnecessary delay and expense to Applicants and duplicative examination by the Patent Office, Applicants respectfully request that the Requirement for Restriction be reconsidered and withdrawn.

If there are any questions concerning this response, or the application in general,

Applicants invite the Examiner to telephone the undersigned at the below-listed number.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: May 29, 2003

Martin A. Bruehs

Registration No. 45,635

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